Suggestions for Organizing Information for a CCOP Application

In preparing a CCOP application, you must follow the instructions provided in the RFA CA-05-014 and the *Application for a Public Health Service Grant* (PHS-398) (revised 5/2001) available at: http://grants.nih.gov/grants/forms.htm and its accompanying packet of forms. The suggestions and sample tables provided in this suggested format are only a supplement to the PHS-398, NOT A REPLACEMENT. However, the attached format may help the applicant to supply all the information required by the RFA while remaining within the page limitations (see Supplemental Instructions in RFA-CA-05-014). Following the suggestions and using the sample tables may assist the reviewers in evaluating the applicant's resources and capabilities. The tables provided in this suggested format may be included in the application as part of the Resources, Progress Report and/or Human Subjects Research sections, as appropriate.

NOTE**: Requirement of DUNS Numbers on NIH Applications** - Effective October 1, 2003, use of the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number will be required when applying for Federal grants or cooperative agreements. See NIH Guide Notice dated August 14, 2003 and the DUNS Q&A (MS Word) document for more information.

NOTE: Other Support should NOT be submitted with the application. If this information is included in the application, the application will be returned to the applicant organization WITHOUT peer review. See pages 43-44 of the PHS 398 (rev. 5/01) instructions.

GENERAL INSTRUCTIONS

Although formatting and submission information is provided in the PHS-398 (rev.5/01), some of the requirements are repeated in these suggested format instructions to emphasize the importance of the submission information in preparing your application**.** Please refer to the RFA CA-05-014 and the PHS-398 (rev. 5/01) for complete instructions.

X Prepare the application single-sided and single-spaced, using the PHS 398 RTF or PDF form/format pages as provided. The print must be clear and legible. Use standard size, black letters that can be clearly copied. The PHS 398 RTF and PDF Form pages as provided are acceptable by NIH. All other sections of the application (e.g., Biographical Sketch, Introduction, and Research Plan) **must conform** to the specifications as outlined on page 3 of the PHS 398 (rev. 5/01) instructions under the heading FORMAT SPECIFICATIONS. You may substitute computer-generated facsimiles for government provided forms: however, they must maintain the exact wording and format of the government forms, including all captions and spacing. You also may create pages similar to the format pages provided in the PHS 398 (rev. 5/01) and the tables in the suggested format (Tables 1 through Table 9B) but these pages must include the requisite information.

X Include all pertinent information in the text and tables. **DO NOT** use appendices for any material that all reviewers need to see because the appendices will not be reproduced for all the reviewers. See PHS 398 (rev. 5/01) pages 29-30, I. Preparing Your Application, 9. Appendix for more details.

X **DO NOT** submit photographs, oversized documents, materials that do not reproduce well, or Institutional public relations-type documents.

- Include a table of contents (see Form Page 3), so that reviewers can identify each part of the application by page number (See PHS 398 (rev. 5/01) page 11, 3. Research Grant Table of Contents) NOTE: Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

CCOP APPLICATION DUE DATE

X Submit the applications **by July 14, 2004**, COB (5:00 pm).

X Affix RFA label to bottom of face page.

X Late applications will NOT be accepted. Receipt dates listed in the PHS 398 (rev. 5/01) II. Submitting Your Application on pages 32-33 **do not apply** to receipt of applications in response to RFA-CA-05-014.

REVISED (AMENDED) APPLICATIONS

An unsuccessful applicant from the previous year=s competition is a revised (amended) application that MUST include an Introduction of not more than three pages that summarize the substantial additions, deletions and changes to the application. The Introduction must also include responses to the criticisms and issues raised in the summary statement. (See **PHS-398 (rev.5/01)**, **I. C. 8., Research Plan, page 15-16**). NOTE: Only two revised (amended) versions of an application are allowed. The two-year restriction on the receipt of the amended applications has been eliminated: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html

COMPETITIVE CONTINUATION APPLICATIONS

An application from a currently funded CCOP is a competitive continuation and must include a progress report (see **PHS-398 (rev. 5/01), I. C. 8. page 17**). The progress report, at a minimum, should include:

X summary of the CCOP activities and accomplishments over the previous funding period, with a clear presentation of accrual (treatment and cancer control) for each year of the funding period (see **Sample Tables 7A and 7B**) of the suggested format;

X an evaluation of the CCOP performance by each of its affiliated research bases;

X complete description of how the applicant has met the special cooperative agreement terms and conditions of the award; and

X report and table on the enrollment of women and men and on the race and ethnicity of research participants during the last year (**see pages 23-26, PHS-398 (rev. 5/01)**).

NEW APPLICATIONS

New applicants are advised to complete all of the Sample Tables, with the exception of the progress reports (**Sample Tables 7A and 7B**) provided in the suggested format. Although the Sample Tables are not required, the reviewers may interpret their absence as an elusive response or lack of data.

SPECIFIC INSTRUCTIONS

The following suggestions for **Section I. C. 7. and 8.** (**pages 15-20**) are listed in the same sequence as the instructions in the PHS-398 (rev. 5/01).

RESOURCES

Use the Resources Format Page (or create pages similar to the format page with the requisite information) and instructions provided in PHS-398 (rev. 5/01) and integrate the following format suggestions to describe Resources (**Section I. C. 7. page 15**).

Patient Catchment/Service Area

Describe the proposed patient catchment service area.

X Include a map of the patient catchment area, designating counties or zip codes from which approximately 80% of the cancer patients will be drawn.

X Describe the geographical area from which patients will be drawn. Include the demographics (age, race, sex, etc.) of the cancer patient population.

X Estimate the percent of oncologists in the service area who will be participating in the CCOP.

X Describe cancer care resources available in the service area that are not part of the CCOP application (e.g., hospitals, clinics, physicians, cancer centers, medical schools, cooperative group affiliate program satellite hospital).

X Estimate the percent of the catchment/service area population that participates in HMOs or PPOs.

X Limit to two pages

Previous Relationships

X Is there a history of previous working relationships among some or all of the proposed participating physicians? If so, describe the following**:**

- previous patient practice relationships (e.g., referral, partnership, group practice, cross coverage);
- previous experience of some or all of the investigators in working together as a group in clinical trials (e.g., common research base, IRB, data management).

X Limit to two pages

Proposed Resources

To assist the applicant in providing material sufficient to permit adequate review of specific areas while maintaining clarity and brevity, we have included the following sample tables as suggested formats for providing specific information regarding proposed resources:

Proposed Resources - continued

Sample Table 1	-	Components
Sample Table 2	-	Affiliates
Sample Table 3A	-	Participating Physicians
Sample Table 3B	-	Non-Physician Investigators (e.g.: PhD=s)
Sample Table 4	-	Personnel
Sample Table 5	-	Number of Newly Diagnosed Cancer Patients by Site
Sample Table 6A	-	Cancer Treatment Research Participation - NCI Protocols
Sample Table 6B	-	Cancer Treatment Research Participation-All Other Protocols
Sample Table 6C	-	Cancer Prevention and Control Research Participation - NCI Protocols
Sample Table 7A	-	Cancer Treatment Participation (Progress Report)
Sample Table 7B	-	Cancer Prevention and Control Participation (Progress Report)
Sample Table 7C	-	Cancer Prevention and Control Research Studies - supported by Other Federal Administrative and Funding Instruments
Sample Table 8	-	Research Base Affiliation(s)
Sample Table 9A	-	Projected Cancer Treatment Protocols Over the Next Year
Sample Table 9B	-	Projected Cancer Prevention and Control Protocols Over the Next Year

NOTE: These tables should be included in the application in Resources, Progress Report and/or Human Subjects Research sections, as appropriate.

RESEARCH PLAN

There is no Form Page for the Research Plan. The research plan should include sufficient information needed for evaluation of the project. Follow the instructions provided in PHS-398 (rev. 5/01) and integrate the following format suggestions to describe the Research Plan (**Section I. C. 8. pages 15-18**).

Preliminary Studies/Progress Report

X **Past Experience**

< Describe your participation in treatment and cancer prevention and control clinical trials during the most recent funding period, or for new applicants, the last 3 years.

< Provide data on the number of patients the CCOP has in active follow-up on NCI-approved treatment trials.

< Describe the outreach activities conducted by the CCOP to attract minority participants.

< Limit to three pages

X **Cancer Treatment Research Participation**

< Enumerate the patient accrual for each physician, either a current CCOP member or a newly proposed member, to cancer treatment trials. Narrative explanation may be attached, if needed, to fully document your experience. Indicate whether the research was funded or sponsored by the NCI, cooperative groups, cancer centers, public health departments, the American Cancer Society, or others. See Sample **Table 6A and 6B** which are intended to reflect the accrual activity by individuals of the CCOP.

< **Sample Table 7A** reflects the accrual to cancer treatment trials for each year of the funding period for the CCOP.

X **Cancer Prevention and Control Research Participation**

< Enumerate the accrual for each physician, either a current CCOP or a newly proposed member, to cancer prevention and control trials. See **Sample Table 6C**. Describe your experience in cancer prevention and control research and related activities.

< **Sample Table 7B** reflects the accrual to NCI approved cancer prevention and control trials for each year of the funding period for the CCOP.

< **If applicable**, provide information about the CCOP=s participation in cancer prevention and control research studies supported through other federal administrative and funding instruments (e.g., R01s, contracts), **Sample Table 7C**. (**Note**: These studies would also be listed on Sample Table 6C by physician.)

< Limit to three pages

X **Evaluation of CCOP Performance by Affiliated Research Bases(s)**

Include copies of reports from affiliated research bases(s) describing CCOP performance over the previous funding period.

Research Design and Methods

Describe the proposed design of the CCOP (**Section I. C. 8. d. page 18**).

X **Operational Plan**

< If the CCOP has more than one component/affiliate, provide a diagram of the CCOP components indicating distances between components/affiliates (including administrative office and shared resources) and location of proposed personnel.

< Describe the relationship of components/affiliates to each other and to the CCOP headquarters.

< Provide information on how the CCOP (physician and staff) will be organized and directed to facilitate clinical treatment and cancer prevention and control research. Include an organizational chart of how the group will function. Describe procedures for assuring implementation of the organizational plan.

< Describe plans for communication among physicians and components/affiliates and incentives for participation.

< Limit to three pages

X **Proposed Data Management**

< Describe the proposed data management plan, including:

- who will have overall responsibility for data management;

- the source of records (e.g., hospital, office, clinic, registry);

- who will be responsible for registering patients/subjects on study;

- how the information will flow (provide flow chart);

- who will be responsible for information entry on primary patient record and on protocol forms (e.g., RN, MD, data manager, secretary);

- who will be responsible for collecting and sending material (e.g., pathology slides, port films, etc.) to the research base if required by a protocol; and

- what records (e.g., protocol flow sheets, forms, reminder slips) if any, will be placed on the patients charts.

< Describe the proposed quality assurance mechanism(s) for treatment and cancer prevention and control protocols. Who will have overall responsibility for quality control?

< Describe in detail the data management operations within and between component/ affiliates, investigators, and the central CCOP administrative office (if applicable).

< Will data be transmitted in batch form or as acquired to an intermediary institution/ central office of the research base(s)? Will this submission procedure be the same for each research base?

< Are computers to be used for data management (e.g., data file, reminder system, protocol data entry, transmittal to research base computers)? Are there provisions for electronic data transfer?

< How will NCI/FDA requirements for control of investigational drugs be met?

< If applicable, describe the involvement of oncology nurses/data personnel in protocol studies not funded by the proposed CCOP award.

< Limit to four pages

X **Proposed Research Base Affiliation(s)**

< Describe previous working relationships with proposed research bases, if applicable. Include information on committee memberships and chairmanships as well as protocols chaired. If one or more components participated as cooperative group affiliate program satellite hospital, specify the years.

< List the current research base affiliation(s) or, for new applicants, the proposed research base affiliation(s). A suggested format is shown in **Sample Table 8**.

< Limit to two pages

X **Cancer Treatment Protocols Proposed for Use by the CCOP**

List the cancer treatment protocols to which the CCOP intends to recruit patients. See **Sample Table 9A** for suggested format.

X **Cancer Prevention and Control Protocols Proposed for Use by the CCOP**

List the cancer prevention and control protocols to which the CCOP intends to recruit participants. See **Sample Table 9B** for suggested format.

X **Detailed Cancer Prevention and Control Description**

< Describe in detail two examples of NCI-approved cancer prevention and control protocol you intend to use from your affiliated research bases (**See CCOP RFA CA-05-014 Submitting An Application, Supplemental Instructions, 1. CCOP Applicants, c.).**

New applicants must provide implementation plans for at least two examples of NCI-approved cancer prevention and control protocols that utilize an intervention. (**See CCOP RFA CA-05-014, Submitting An Application, Supplemental Instructions, 1. CCOP Applicants, c.** paragraph 3).

< Describe the current and future outreach activities that the CCOP will conduct to attract minority participants.

Data-Sharing Plan

All applicants must address their data sharing plan in their application. Data sharing pertains to both published and unpublished but complete data sets. While a CCOP application does collect data on individual patients/participants entered onto clinical trials, the research base(s) is the entity that receives the collective data on protocols for which it is the lead group. The research base(s) will ultimately share these data through publications, presentations and other mechanisms deemed to be appropriate. Investigators should refer to the NIH Guide: Final NIH Statement on Sharing Research Data (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html and http://grants.nih.gov/grants/policy/data_sharing/) for guidance on addressing this application requirement.

< Describe the CCOP's plan to share data. Include a brief paragraph describing how the CCOP shares its data with its affiliated research bases and/or through other mechanisms, if applicable. Describe the process the CCOP follows to protect the rights and confidentiality of patients/participants.

Human Subjects Research

- Create a section heading Human Subjects Research immediately following the last entry in the Research Design and Methods section.

  < Address the involvement of human subjects and protections from research risk relating to their participation in the purposed research plan. Include a discussion of potential risks to research participants posed by data sharing and steps that are taken to address those risks. See the Table Guidance for Preparing the Human Subjects Research Section on pages 19-20 of the PHS 398 (rev. 5/01). CCOPs should refer to scenario C for preparing this section. Refer to Data and Safety Monitoring Plan section below.

- Create a section entitled "Protection of Human Subjects." See pages 20-21 of the PHS 398 (rev.5/01) instructions for the four criteria that need to be addressed in this section.

  < Provide verification of completion of education on the protection of human research participants for all investigators involved in the design or conduct of research involving human subjects. All physicians accruing patients/participants to clinical trials must complete this training. Refer to the following URL address for further guidance: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Women and Minority Inclusion in Clinical Research

- Create a section entitled "Inclusion of Women," and a **separate section** entitled "Inclusion of Minorities. These sections must follow immediately after the Human Subjects Research section. See pages 22-24 of the PHS 398 (rev. 5/01) instructions.

Inclusion of Children

- Create a section heading entitled Inclusion of Children. This section should immediately follow the Women and Minority Inclusion in Clinical Research section.

  < For CCOPs that do include a pediatric component the plan for including children should be described. See the PHS 398 (rev, 5/01) instructions on page 26 for added guidance on information to include in your description.

  < If children will be excluded from the research, the applicant must present an acceptable justification for the exclusion. For CCOP applicants that do not include a pediatric component see Justifications for Exclusion of Children pages 26-27 1. b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network.

Data Safety and Monitoring Plan

- Create a section heading entitled "Data and Safety Monitoring Plan."

  < Although a CCOP applicant is not directly responsible for the formulation of data safety and monitoring plans and/or boards, the applicant should discuss the fact that the CCOP follows the data safety and monitoring plan(s) for each of the CCOP research bases with which it affiliates. Provide a description of how the CCOP implements the research base(s) plan.